

Application No.: 09/628,387  
Filing Date: August 1, 2000  
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Attorney Docket No.: ABI1150-18  
(071243-0218)

### **Remarks**

In accordance with the present invention, there are provided unit dosage forms of cremophor-free paclitaxel which allow systemic administration to a human subject in need thereof at doses and over administration periods and/or treatment cycles not previously possible. Due in part to the ability to deliver paclitaxel in the absence of cremophor, invention unit dosage forms provide paclitaxel in amounts which exceed previously accepted levels for maximum dosages. The larger doses of paclitaxel provided by invention unit dosage forms afford both markedly improved therapeutic benefits and dramatically reduced administration periods, thereby alleviating discomfort experienced by a subject in need of treatment with paclitaxel.

By the present communication, claims 1-3, 12-16, 58-60, 74-78, 128-131 and 145-147 are pending in this application. Claims 4-11, 17-57, 61-73, 79-127, 132-144 and 148-177 were previously canceled.

### **Double Patenting**

The Office Action has provisionally rejected claims 1-3, 12-16, 58-60, 74-78, 128-131 and 145-147 under the judicially created doctrine of double patenting over claims 179-181, 190-192, 205-208, 216-218 and 220 of copending Application No. 09/629,501. While not acquiescing to the Examiner's rejection, in order to reduce the issues and expedite prosecution, Applicant submits herewith a terminal disclaimer, disclaiming the portion of any patent to issue on the present application which would extend beyond the term of copending Application No. 09/629,501. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

### **Claim Rejection – 35 U.S.C. § 112**

The rejection of claims 1-3, 12-16, 58-60, 74-78, 128-131 and 145-147 under 35 U.S.C. § 112, first paragraph, as allegedly being based on a disclosure which is not enabling is respectfully traversed. Applicants respectfully disagree with the Examiner's assertion that "[i]n order to utilize the system as claimed, the skilled artisan would be presented with an

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unpredictable amount of experimentation." Specifically, Applicants respectfully disagree with the Examiner's assertion that "an undetermined number of experimental factors would be necessary to create a cremophor free unit dosage form comprising taxane."

Contrary to the Examiner's assertion, support for the preparation of unit dosage forms of cremophor-free paclitaxel is found throughout the specification. For example, the specification describes cremophor-free paclitaxel beginning on page 10, and provides exemplary procedures for the preparation of unit dosage forms of cremophor-free paclitaxel in Example 12 (see, page 41, lines 12-24). Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

#### Conclusion

In view of the above amendments and remarks, prompt and favorable action on all claims is respectfully requested. In the event any matters remain to be resolved in view of this communication, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

Respectfully submitted,

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